(3)

No. 83-1925

In the Supreme Court of the United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA, ET AL., APPELLANTS

v.

AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

REX E. LEE
Solicitor General

RICHARD K. WILLARD
Acting Assistant Attorney General

JOHN F. CORDES
MARGARET E. CLARK
Attorneys

Department of Justice
Washington, D.C. 20530
(202) 633-2217

QUESTION PRESENTED

Whether Hillsborough County Ordinances 80-11 and 80-12 and their implementing rules and regulations pertaining to the collection of blood plasma from paid donors are preempted by regulations adopted by the Food and Drug Administration governing blood and blood products, including blood plasma and plasmapheresis.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Constitution, statutes and regulations:

In the Supreme Court of the United States

OCTOBER TERM, 1984

No. 83-1925

HILLSBOROUGH COUNTY, FLORIDA, ET AL., APPELLANTS

v.

AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE
UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's invitation to the Solicitor General to express the views of the United States.

STATEMENT

1. Pursuant to the provisions of the Public Health Service Act, 42 U.S.C. 262 *et seq.*, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 *et seq.*, the Department of Health and Human Services (HHS) is authorized to regulate blood and blood products as biological products (42 U.S.C. 262) and

as drugs (21 U.S.C. 321(g)(1)). Under Section 351 (a) of the Public Health Service Act, 42 U.S.C. 262 (a), manufacturers and vendors of biological products, including blood products and their derivatives, must be licensed by the Secretary of Health and Human Services. Licenses are issued only upon a showing that the manufacturer's or vendor's establishment and products meet certain safety, purity, and potency standards established by the Secretary. HHS is authorized to inspect such establishments for compliance as it sees fit (42 U.S.C. 262(d) and (c)).

Pursuant to Section 351, the Food and Drug Administration's Office of Biologics Research and Review, as the designee of the Secretary,[1] regulates various types of blood products and blood banking activities, including blood plasmapheresis procedures. 21 C.F.R. Pts. 600, 601, 606, 607, 610, 640.[2] Under 21 C.F.R. Part 640, Subpart G, the FDA has established standards for plasma collected by plasmapheresis. 21 C.F.R. 640.60-640.76. These standards were adopted, and are revised from time to time, to ensure the safety, purity, and potency of the final products derived from plasma[3] and to protect plasmapheresis donors from possible abuses ranging from the collec-

[1] Pursuant to Section 361 of the Public Health Service Act, 42 U.S.C. 264, and under authority delegated to him (21 C.F.R. 5.10), the Commissioner of Food and Drugs is authorized to promulgate regulations.

[2] Plasmapheresis is defined as "the procedure in which blood is removed from the donor, the plasma is separated from the formed elements and at least the red blood cells are returned to the donor." 21 C.F.R. 606.3(e).

[3] Plasma derivatives include such products as hepatitis vaccine, albumin, and antihemophilic factor. See, *e.g.*, 21 C.F.R. 610.41, 640.50, 640.80.

tion of excessive quantities of plasma to the use of medical or collection procedures that could endanger a donor's health. See 39 Fed. Reg. 26161 (1974). The regulations require, inter alia, that a plasma center obtain the informed consent of donors before plasmapheresis is performed and that a licensed physician both examine a potential donor before he or she is accepted and be present on the premises while the procedure is being performed. 21 C.F.R. 640.61-640.63. The regulations establish minimum standards for donor eligibility, for conducting plasmapheresis, and for processing, storing, and labelling plasma units obtained during the procedure. 21 C.F.R. 640.63, 640.65, 640.68, 640.70. Recordkeeping requirements are also imposed. 21 C.F.R. 640.72. The Director of the Office of Biologics Research and Review has the power to approve variances from any of the requirements of Subpart G. 21 C.F.R. 640.75.

2. a. In November 1980, Hillsborough County, Florida adopted County Ordinances 80-11 and 80-12 (J.S. App. A29-A39), which govern the licensing and operation of commercial blood plasma donor centers. Ordinance 80-11 imposes a license fee on plasmapheresis centers, while Ordinance 80-12 "provide[s] a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest of the health of the people of Hillsborough County" (J.S. App. A32-A33). In addition to incorporating by reference the FDA's blood plasma regulations (*id.* at A38-A39), Ordinance 80-12 imposes certain additional donor testing and recordkeeping requirements not contained in 21 C.F.R. Subpart G. Among other things, Ordinance 80-12 requires that plasma vendors be issued county identifi-

cation cards that restrict them to donating at one particular center; it also requires that each donor be tested for hepatitis prior to registration [4] and be given a breath analysis for alcohol content before each plasma donation. Ordinance 80-12, §§ 4, 6(A), 7 (J.S. App. A33-A34, A35-A36).

b. Appellee Automated Medical Laboratories, Inc. (AML) is a Florida corporation that operates, through subsidiary corporations, eight blood plasma centers in the United States, including Tampa Plasma Corporation (TPC), in Hillsborough County. Following Hillsborough's adoption of Ordinances 80-11 and 80-12, appellee filed this action against the county and its health department in the United States District Court for the Middle District of Florida, challenging the constitutionality of the ordinances and the rules and regulations adopted to implement them. In November 1982, the court issued an opinion sustaining the ordinances and regulations (J.S. App. A13-A19). The court found no evidence of "express congressional intent to occupy the entire field of assuring high standards of practice in plasmapheresis" and concluded that the ordinances supplemented the federal regulations, rather than conflicting with them (*id.* at A17). The court also held that the ordinances did not violate the Equal Protection Clause of the Fourteenth Amendment and that most of the challenged provisions did not impermissibly burden interstate commerce (J.S. App. A18). With respect to the breathalyzer requirement, however, the court held that the county had not demonstrated that such a provision would serve the public interest to any

[4] Under federal regulations, testing for hepatitis-positive plasma is performed after plasmapheresis is completed. See 21 C.F.R. 640.67, 640.75.

greater degree than the federal regulations (*id.* at A19). Accordingly, the court held that the provisions relating to that requirement (Section 7 of Ordinance 80-12 and Section 4 of the implementing Rules and Regulations (J.S. App. A35-A36, A41)) impermissibly burdened interstate commerce and were invalid (J.S. App. A19).

c. The court of appeals reversed in part, holding that the FDA's blood plasma regulations preempted all provisions of the county ordinances (J.S. App. A1-A12). The court of appeals first noted that the federal regulatory scheme was "comprehensive" and stated that its "pervasiveness * * * makes it reasonable to infer that Congress left no room for local ordinances to supplement it" (*id.* at A8-A9). The court also concluded, based on statements by the FDA regarding the establishment of a National Blood Policy, that the field of plasmapheresis was one in which the federal interest was dominant over any state or local interest (*id.* at A10). Finally, the court concluded that the additional requirements imposed on plasma centers by the county ordinances were "burdensome and expensive" and would interfere with "the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors" (*id.* at A11).

DISCUSSION

1. When acting within constitutional limits, Congress is empowered to preempt state law by so stating in express terms. *Jones* v. *Rath Packing Co.*, 439 U.S. 519, 525 (1977). In the absence of express preemptive language, Congress's intent to preempt state law completely in a particular area may be inferred either because " '[t]he scheme of federal regulation may be so pervasive as to make reasonable the infer-

ence that Congress left no room for the States to supplement it,' because 'the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject,' or because 'the object sought to be obtained by federal law and the character of obligations imposed by it may reveal the same purpose.'" *Fidelity Federal Savings & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982), quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Even where Congress has not completely displaced state regulation in a specific area, state law is preempted to the extent that it actually conflicts with federal law, either because it proves impossible to comply with federal and state law simultaneously (*Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132, 142-143 (1963)) or because state law stands as an impediment "to the accomplishment and execution of the full purposes and objectives of Congress" (*Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). These preemption principles apply with equal force to federal statutes and regulations. *Fidelity Federal Savings & Loan Ass'n* v. *de la Cuesta*, 458 U.S. at 153.

As this Court has repeatedly cautioned, however, preemption will not be presumed absent a clear manifestation of congressional or agency intent to supersede state legislation. *New York Department of Social Services* v. *Dublino*, 413 U.S. 405, 413 (1973). As the Court noted in *Dublino* (*id.* at 415), "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." Accord, *De*

Canas v. *Bica*, 424 U.S. 351, 359 (1976). Thus, the Court has frequently rejected preemption attacks on laws enacted pursuant to a state's police powers that paralleled federal law on the same subject or imposed more stringent requirements. *Pacific Gas & Electric Co.* v. *State Energy Resources Conservation & Development Comm'n*, 461 U.S. 190 (1983) (California statute conditioning construction of nuclear power plants on certain findings by state agency not preempted by federal law); *Florida Lime & Avocado Growers, Inc.* v. *Paul*, *supra* (California statute prohibiting importation of avocados with oil content below a certain value not preempted by Department of Agriculture marketing order allowing interstate shipment of avocados whose maturity was measured by a different standard); *Huron Portland Cement Co.* v. *City of Detroit*, 362 U.S. 440 (1960) (sustaining city's smoke abatement code against claim that federal inspection laws for maritime vessels preempted such local regulation); *California* v. *Zook*, 336 U.S. 725 (1949) (state law prohibiting same conduct by motor carriers that was prohibited by federal law not preempted); *Maurer* v. *Hamilton*, 309 U.S. 598 (1940) (Pennsylvania statute prohibiting operation on state highways of "above the cab" carrier vehicles not preempted by Interstate Commerce Commission's licensing of such vehicles to operate interstate). "'[P]reemption of state law by federal statute or regulation is not favored in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained.'" *Alessi* v. *Raybestos-Manhattan, Inc.*, 451 U.S. 504, 522 (1981) (citations omitted).

2. With one specific exception, the FDA's blood plasma regulations do not, in our view, preempt Hillsborough County Ordinances 80-11 and 80-12. As the court of appeals acknowledged (J.S. App. A7), neither the federal blood plasma regulations nor the statutes upon which they are based expressly state an intention to preempt state law. Nonetheless, the court of appeals concluded that the county's ordinances were implicitly preempted based on three factors: the "comprehensive" nature of the federal regulations (*id.* at A8-A9), the "dominan[ce]" of federal interest in the field of blood plasma regulation (*id.* at A9-A10), and the court's perception that enforcement of state law would present a "serious danger of conflict" with the administration of the federal regulations (*id.* at A10-A11). Except with respect to one provision of the ordinances, we disagree with the court of appeals' conclusion.

a. As the court of appeals itself noted (J.S. App. A9), the fact that the FDA's blood plasmapheresis regulations are broad in scope and cover most aspects of the plasmapheresis process does not establish that the agency intended completely to displace state or local regulatory efforts in the same area. Given the complexity and technical nature of the subject, a detailed regulatory approach "was both likely and appropriate, completely apart from any questions of pre-emptive intent." *Dublino*, 413 U.S. at 415; see also *DeCanas*, 424 U.S. at 359. Accordingly, no inferences in favor of preemption can or should be drawn solely from the detailed nature of the federal plasmapheresis regulations.

b. The court of appeals erred in finding that the federal interest in the area of blood plasmapheresis is so dominant as to preclude state or local

laws that serve valid local interests and do not interfere with the FDA's regulatory scheme. Because blood products are widely distributed in interstate and foreign commerce, rather than being produced and used locally, the court of appeals may have been correct that insuring a safe, pure, and adequate supply of blood plasma is predominantly a federal rather than a state or local concern. However, state and local governments have a strong traditional interest in protecting the health of their citizens. Cf. *Head* v. *New Mexico Board of Examiners in Optometry*, 374 U.S. 424, 428 (1963) (statutes addressed to protection of public health fall "within the most traditional concept of what is compendiously known as the police power"). Protection of blood donors and vendors within their jurisdictions is a legitimate exercise of this authority. States and localities have also historically shared with the federal government an interest and an active role in assuring a safe and adequate supply of blood. For example, many federally licensed blood banks are concurrently licensed by the states in which they are located. Accordingly, we are not prepared to say that the federal government's interest in regulating blood and plasma products is so dominant that it precludes enforcement of state laws that are consistent with the federal regulatory scheme.[5]

---

[5] The National Blood Policy referred to by the court of appeals (J.S. App. A9) was established in 1974 by the Department of Health, Education, and Welfare as "a pluralistic and evolutionary approach to the solution of blood collection and distribution problems" (39 Fed. Reg. 32702) and was designed to stress cooperative efforts among the federal government and the public and private sectors (*id.* at 32703). Although FDA statements at the time this policy was an-

c. It follows that Hillsborough County's ordinances are not preempted unless it is impossible to comply with them without violating the FDA's regulations or without frustrating the objectives of the federal regulatory program. Here, "compliance with both federal and state regulations is [not] a physical impossibility." *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. at 142-143. Indeed, Hillsborough County's ordinances expressly incorporate the FDA's plasmapheresis regulations, and nothing in the ordinances or implementing regulations requires actions that would violate the federal rules.

With one specific exception, it also does not appear at this time that the Hillsborough ordinances and regulations "stand[] as an obstacle to the accomplishment * * * of the full purposes and objectives of [the FDA]." *Hines* v. *Davidowitz*, 312 U.S. at 67. The Hillsborough provisions requiring local licensing, certification of donors, recordkeeping, reporting, and inspection are more stringent than but are not inconsistent with federal regulations. The court of appeals concluded (J.S. App. A11) that these provisions are "burdensome and expensive" and that they threaten "the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors." Overly restrictive local legislation could threaten the national plasma supply, but

---

nounced recognized the significant role federal regulation was likely to play in its implementation, the policy, as originally announced, expressly stated that it was not intended to encompass the plasmapheresis area, which was to be addressed at a later date (*id.* at 32702). Moreover, nothing in this policy statement suggested that HEW or the FDA had any intention to regulate blood banking activities to the exclusion of state or local governments.

at this time the FDA has not identified such a threat.[6] Should a threat become apparent, the FDA would possess the authority to issue regulations preempting such local legislation. The FDA's present regulations were not intended to have this effect.

In one respect, however, the county's regulations and ordinances do conflict with federal regulations. Pursuant to Section 6(D) of Ordinance 80-12 and Section 2.B of the implementing Rules and Regulations (J.S. App. A35, A40), plasma donors are prohibited from undergoing plasmapheresis until an examining physician issues a "Certificate of Good Health as required by [FDA] regulations." Under 21 C.F.R. 640.75, the FDA authorizes specific plasmapheresis facilities to collect blood from donors who have tested positive for hepatitis B surface antigen or have other conditions that render them, by any reasonable medical description, not in "good health" as required by 21 C.F.R. 640.63(c). Collection of plasma from such individuals, under carefully controlled conditions, is necessary to produce the vaccine used to prevent hepatitis (21 C.F.R. 610.41), as well as the diagnostic products used to identify the presence of disease. Accordingly, Hillsborough's ordinances and regulations are preempted to the extent that they preclude donors who are or have been hepatitis-reactive or who are otherwise not in good health from donating plasma in a manner consistent

---

[6] Similarly, the district court found in this case (J.S. App. A15) that appellee's claims of burden and added expense in complying with the ordinances were speculative and that there was no factual basis in the record for appellee's claim that the donor population would decrease significantly if the ordinances were enforced. The court of appeals identified no basis for concluding that these findings were erroneous.

with specific exemptions granted by the FDA under 21 C.F.R. 640.75.

The primary objectives of the FDA's plasmapheresis regulations are to ensure that plasma can be collected in such a way as to assure the "safety, purity, and potency" of the final products to be manufactured from it, as well as to protect plasmapheresis donors. 39 Fed. Reg. 26161 (1974). The agency believes that its standards, if complied with, are fully adequate to achieve both of these goals. Nonetheless, with the limited exception noted above, the Hillsborough County ordinances in question here are not inconsistent with the dual federal goals of product and donor safety. Under these circumstances, and in the absence of any evidence that implementation of these local ordinances will have a significant adverse impact on the availability of plasma donors, the government believes that there is no basis for finding complete preemption in this case.

CONCLUSION

Probable jurisdiction should be noted.

Respectfully submitted.

REX E. LEE
Solicitor General

RICHARD K. WILLARD
Acting Assistant Attorney General

JOHN F. CORDES
MARGARET E. CLARK
Attorneys

DECEMBER 1984

☆ U. S. GOVERNMENT PRINTING OFFICE: 1984 461531 10112